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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,506	09/19/2000	Paolo Cozzi	P101615-0007	9195

7590

06/17/2003

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,506

Applicant(s)

COZZI ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 10, 2002 has been entered.

2. Claims 2, 3, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, part (b), Formula (IV), the bond sign which should be present in the acryloyl group is missing. Claims 2 and 3 define variables R_4 - R_8 and R_{10} - R_{12} which are no longer present in the independent claim, and claim 3 permits B to be substituents no longer permitted by the independent claim. It is not clear if substituents and variables were inadvertently omitted from independent claim 12, or if substituents and variables should be deleted from claims 2 and 3.

3. Claim 12 is objected to because of the following informalities: In claim 12, in the definition of B, the comma between the two structural formulas should be replaced with "and". Appropriate correction is required.

4. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2 and 3 define variables R_4 - R_8 and R_{10} - R_{12} which are no longer present in the independent claim, and claim 3 permits B to be substituents no

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longer permitted by the independent claim. See also the above rejection under 35 U.S.C. 112, second paragraph.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 2-12 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/04524 in view of the WO Patent Application 96/05196. The WO Patent Application '524 teaches acryloyl-substituted distamycin derivatives useful as antitumor agents which differ from Applicants' claimed compounds in that the compounds of the WO Patent Application '524 contain only pyrrole as the heterocyclic ring, whereas Applicants' claims require at least one of the heterocyclic rings to be other than pyrrole. The WO Patent Application '196 teaches the substitution of pyrrole rings in a distamycin A analog either partially or completely with other heteromonocyclic rings, especially with imidazole or pyrazole rings (see, e.g., the Abstract; page 1, lines 12-14; page 5, lines 17-18; and pages 7-18). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute imidazole or pyrazole rings for some or all of the pyrrole rings of the compounds of the WO Patent Application '524 because the WO Patent Application '196 teaches such substitutions in analogous distamycin compounds and because the resulting compounds have only the expected antitumor activity.

6. Claims 2-12 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/04524 in view of the WO Patent Application 96/05196 as applied against claims 2-12 above, and further in view of the Baraldi et al article. As noted above, the WO Patent Application '524 does not teach a compound in which at least one of the heterocyclic rings is

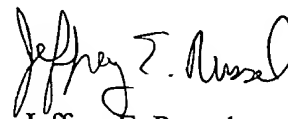
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other than pyrrole. The Baraldi et al article teaches distamycin derivatives 12 and 13 comprising an initial imidazole or pyrazole ring which has improved in vivo antitumor activity in comparison with distamycin derivative 3 which has an initial pyrrole ring. See, e.g., page 1241; Scheme 1; and page 1244, Table 1. Accordingly, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute an imidazole or pyrazole ring for the initial pyrrole ring in the distamycin derivatives of the WO Patent Application '524 because the WO Patent Application '196 teaches such ring substitutions in analogous distamycin compounds and because the Baraldi et al article suggests that such a substitution would have been expected to increase the in vivo antitumor activity of a distamycin derivative.

7. Applicant's arguments filed September 10, 2002 have been fully considered but they are not persuasive. The examiner maintains his position for the reasons set forth during the previous prosecution of this application.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
June 13, 2003